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| 10/520,786 | 01/11/2005 | John Michael Leadbeater | Q85726 | 2429 |
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| DEES, NIKKI H | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,786

Applicant(s)

LEADBEATER ET AL.

Examiner

Nikki H. Dees

Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-30 and 32-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-30 and 32-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S5108)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed April 29, 2009, has been entered. Claims 1, 2, 4-30, and 32-71 are currently pending in the application. Claim 31 has been cancelled. The previous objections to claims 31, 32, 51, 58, and 59 have been withdrawn in view of the amendments to these claims and the cancellation of claim 31. The previous 112 rejection of claims 39 and 65 have been withdrawn in view of the amendments to claims 39 and 65.

Claim Objections

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the lower limit of the weight percent range for the gum base in claim 44 is not supported in the specification (p. 4 lines 1-6).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 1, 2, 4, 12, 14-19, 23-30, 32-34, 36, 37, 39-41, 43, 44, and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Beringer et al. (4,139,589).
5. Beringer et al. teach a chewing gum product in the form of a multilayered tablet and process for making the tablet (Abstract). The layers are compressed to form a joint tablet comprising at least one tablet mass and one chewing gum mass (col. 1 lines 31-34). The granulate material may be mixed in a number of ways, including mixing the chewing gum granulate with non-plastic tablet mass, followed by pelletizing (col. 2 lines 20-24). Their Example 2 teaches a three-layered tablet with the middle layer comprising a gum base (chicle gum) and tablet base (sugar), as well as two outer layers comprising a tablet base (sorbitol). The gum base is present at about 60 % in Example 2 (col. 8). The layers are taught as being arranged one on top of another, as well as completely enclosed (Figs. 7-8). Beringer et al. further state that the different layers of their product may have different substances mixed in and/or be different colors (col. 4 lines 8-12). The tabletted product may also comprise an active ingredient including pharmaceuticals (col. 1 lines 26-34). The active ingredient (eucalyptus oil) is taught in the second material in Example 2. As the product comprises sugar, it is considered to contain a nutritive (caloric) ingredient. These teachings anticipate Applicants' claims 1-4, 12, 14, 15, 17-19, 25-30, 32-34, 36, 37, 39-41, 43, 44, and 71.
6. Beringer et al. state that their product may have one layer that is hard and one layer that is plastic (col. 1 lines 31-34). This would result in an initial crunchy then chewy sensation, thus anticipating Applicants' claim 16.

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7. Beringer et al. also prepare their layered tablet with an indentation. The first layer is compressed with an indentation. The second part (gum base) is added to the material. An additional layer is fed into the press and compressed to cover the plastic mass (gum base) inserted in the center (Fig. 6 and col. 5 lines 7-17). These teachings anticipate Applicants' claims 23 and 24.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 5-7, 13, 20-22, 35 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beringer et al. (4,139,589).

10. Beringer et al. teach a layered tablet chewing gum as applied to claims 1, 25, and 39 above.

11. Beringer et al. are silent as to the layers having a different thickness and to the gum base material and tablet base material being particulated before being combined.

12. Regarding claims 5-7, 13, 35, and 42, it would have been obvious for one of ordinary skill in the art at the time the invention was made to have varied the thickness of the layers as taught by Beringer et al. in order to provide more (or less) of one of the components of the tablet. As the thickness of the layers may be varied, the weight ratio

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of the layers may also be varied. The tablet as taught by Beringer et al. could be easily modified by one of ordinary skill without undue experimentation. There would have been a reasonable expectation that the resulting tablet would maintain its favorable chewing gum properties.

13. Regarding claims 20-22, Beringer et al. teach a process for making their layered tablet. The granulate material may be mixed in a number of ways, including mixing the chewing gum granulate with non-plastic tablet mass, followed by pelletizing (col. 2 lines 20-24). The chewing gum base may be mixed with the tablet base (Example 2, col. 8). The tablet mass is granular and pelletized. The granulate gum base is then pressed to the plastic (tablet base) portion of the tablet (col. 2 lines 3-11). Additional layers may be added as shown in Fig. 10 and col. 6 lines 30-45.

14. In the process of Beringer et al., the gum base and tablet material are mixed, granulated, and then compressed. Applicant's claims are to the particulated gum base and particulated tablet material presented separately, mixed, and then compressed. The selection of any order of performing process steps is considered to be *prima facie* obvious in the absence of new or unexpected results. See *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946). In the instant case, both the method of Beringer et al. and the claimed method result in a particulate material that is compressed into a tablet. As this result is neither new nor unexpected, the claimed process is considered to be obvious over the prior art.

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15. Claims 8-10, 53, and 55-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beringer et al. (4,139,589) in view of Cherukuri et al. (4,753,805).

16. Beringer et al. teach a chewing gum product in the form of a multilayered tablet and process for making the tablet (Abstract). The layers are compressed to form a joint tablet comprising at least one tablet mass and one chewing gum mass (col. 1 lines 31-34). Their Example 2 teaches a three-layered tablet with the middle layer comprising a gum base (chicle gum) and tablet base (sugar), as well as two outer layers comprising a tablet base (sorbitol). The gum base is present at about 60 % in Example 2 (col. 8). The layers are taught as being arranged one on top of another, as well as completely enclosed (Figs. 7-8). Beringer et al. further state that the different layers of their product may have different substances mixed in and/or be different colors (col. 4 lines 8-12). The tableted product may also comprise an active ingredient including pharmaceuticals (col. 1 lines 26-34). The active ingredient (eucalyptus oil) is taught in the second material in Example 2. As the product comprises sugar, it is considered to contain a nutritive (caloric) ingredient.

17. Beringer et al. are silent as to the same sugar or polyol being used as the tablet base in both the first (gum base) and second (outer layer) of their invention. Beringer et al. are silent as to the use of a plasticized rubber or polymer for the gum base. They are also silent as to their invention containing a dental vehicle or breath freshener.

18. Cherukuri et al. teach a tableted chewing gum composition that is made by compression (Abstract). Their invention is taught with both a nutritive sweetener (sugar) and sugar-free using sorbitol (col. 11 Examples IV and V). Cherukuri et al. teach a

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number of compounds that may be use for the gum base including polymers (col. 6 lines 14-20). They also teach their invention comprising fluorides for tooth decay (col. 9 lines 34-35) and flavoring agents including spearmint oil and oil of wintergreen (col. 8 line 1).

19. Regarding claims 8 and 10, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a polyol as taught by Cherukuri et al. along with gum base, as well as in the outer layers as taught by Beringer et al.

Beringer et al. teach the use of sorbitol in the outer layer (Example 2) and Cherukuri et al. teach the use of sorbitol blended with the gum base for the production of a tabletted chewing gum. One of ordinary skill desiring to produce a sugar free product would be able to substitute sorbitol for the sugar in the invention of Beringer et al. This would not have required undue experimentation on the part of the artisan, and the resultant sugar-free product would have been expected to maintain its favorable taste and chewing properties.

20. Regarding claims 9 and 53, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized a chewing gum base other than the chicle as taught by Beringer et al. One of ordinary skill would have been familiar with other gum bases as taught by Cherukuri et al. and would have been able to substitute a different gum base for the chicle without undue experimentation in order to impart the desired "chewiness" in their product. There would have been a reasonable expectation that the resultant product would have maintained its favorable chewing properties.

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21. Regarding the different colors providing contrasting effects, the selection of colors for the different layers is considered an obvious matter of choice depending on the effects one of ordinary skill wishes to convey. As Beringer et al. teach that the layers of their product may be different colors, the selection of contrasting colors is considered obvious and not considered to provide any patentable distinction over the teachings of the prior art.

22. Regarding claims 65-66, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the flavoring agents and fluorides to prevent tooth decay as taught by Cherukuri et al. with the chewing gum composition as taught by Beringer et al. The composition of Beringer et al. is taught comprising other pharmaceutical agents, though not the specific ones as claimed. One of ordinary skill could have taken the additional components as taught by Cherukuri et al. and added them to the composition of Beringer et al. without undue experimentation. The resultant product would have been expected to have the desired dental vehicle or breath freshening properties while still maintaining its favorable chewing and taste properties.

23. Claims 11, 38, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beringer et al. (4,139,589) in view of Fisher et al. (4,370,350).

24. Beringer et al. teach a layered tablet chewing gum product as applied to claims 1, 25, and 39 above.

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25. Beringer et al. are silent as to the particle size of the gum base material and tablet base material.

26. Fisher et al. teach a tabletted chewing gum product made by compression (col. 1 lines 65-67). They go on to state that the particles being compressed passed through a 20 to 80 mesh screen (177 μm to 841 μm) and easily tableted on conventional machinery (col. 4 lines 56-58).

27. Regarding claims 11, 38, and 45, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the particle size as taught by Fisher et al. for the production of the tabletted chewing gum product of Beringer et al. The products are being produced by the same technology, and Fisher et al. state that they have favorable results when tableting their product. Therefore, it would have been obvious to use the same particle size in the layered product of Beringer et al. There would not have been undue experimentation required to make this modification to the product of Beringer et al., and the resultant tablets would have been expected to maintain their chewing and flavor characteristics.

28. Claims 46-52 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beringer et al. (4,139,589) in view of Cherukuri et al. (4,753,805) and in further view of Fisher et al. (4,370,350).

29. Beringer et al. in view of Cherukuri et al. teaches a gum base in the form of polymers as detailed above.

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30. Beringer et al. in view of Cherukuri et al. is silent as to the size of the particles to be compressed.

31. Regarding claims 46-52, the product of Beringer et al. is taught as having multiple layers of the same thickness as detailed above. The product also comprises about 60% of gum base (chicle) and the layers may be different colors, also as detailed above.

32. Beringer et al. are silent as to the particle size of the gum base material and tablet base material.

33. Fisher et al. teach a tabletted chewing gum product made by compression comprising particles ranging in size from 20 to 80 mesh (177 μm to 841 μm) as noted above.

34. Motivation for combining Beringer et al. and Fisher et al. in respect to claims 46-52 and 54 is the same as the motivation as applied above to claims 11 and 38. One of ordinary skill in the art would have expected this combination to result in a favorable chewing gum tablet.

35. Regarding claim 49 and the varying of the thickness of the layer, motivation for the variations in these thicknesses are the same as applied to claims 5-6 above. The adjustment of the thickness of the layers would not have required undue experimentation, and would not have adversely affected the efficacy of the product.

Response to Arguments

36. Applicant's arguments filed April 29, 2009, have been fully considered but they are not persuasive.

37. Applicant's arguments, see Remarks pp. 16-17, directed to the amended claim 1 are not persuasive.

38. As detailed in the rejection *supra*, Beringer et al. teaches that the plastic gum base material granulate of their invention may be mixed with the non-plastic tablet mass, followed by pelletizing. There are then present zones of the individual granulate particles (col. 2 lines 20-24). This teaching is considered to meet Applicants' amended claim 1 wherein a first integral part of the instant invention comprises a compressed mixture of particulated gum base material and separate particulated tablet base material. This teaching of Beringer et al. does not provide for a common, blended mass of material, as alleged by Applicant.

39. Applicants' results reported in Experimental Test Report HE4 are not convincing of unexpected results over the prior art as, again, Beringer et al. teaches that the plastic gum base material granulate of their invention may be mixed with the non-plastic tablet mass, followed by pelletizing to provide zones of the individual granulate materials. This would give rise to the same crunchiness as Applicant alleges is unexpected over the teachings of the prior art.

40. Regarding amended claim 53, Applicants argue that the layered product of Beringer et al. does not provide any means to indicate whether deterioration of the layers has occurred (Remarks, p. 21).

41. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the layers indicating inappropriate storage condition) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

42. Applicants' claims require "distinctive visual indication" in the layers. As Beringer et al. teach that the layers of their chewing gum product may be different colors, the teachings of the prior art are considered to meet this limitation. Applicant's arguments that the tablet of Beringer would not show evidence of degradation, as the instant tablet allegedly would, are not persuasive as this limitation is not claimed. Additionally, there is no support in Applicant's specification for the distinctive coloration, or lack thereof, between the layers to provide any indication as to whether or not the tablet has been treated inappropriately.

43. Applicant argues (Remarks, p. 22) that one of ordinary skill would not have combined Beringer and Cherukuri as the tablet of Cherukuri contains only one integral part.

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44. The teachings of Cherukuri to a single-layer gum product would not have prevented one of ordinary skill from employing gum bases and flavors as taught into gum products of more than one layer. The “small amount” of gum material relative to the tablet weight of Beringer would not have precluded the combination of the references.

45. Applicant's arguments (Remarks, p. 22) directed to the combinations of Beringer with Fisher and Cherukuri are addressed *supra*.

Conclusion

46. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki H. Dees whose telephone number is (571) 270-3435. The examiner can normally be reached on Monday-Friday 7:30-5:00 EST (second Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. H. D./
/Lien T Tran/
Primary Examiner, Art Unit 1794

Nikki H. Dees
Examiner
Art Unit 1794